

REMARKS/ARGUMENTS

Reconsideration of this application is requested. Claims 16-25 are in the case.

I. THE ANTICIPATION REJECTION

Claims 16-19, 21, 22, 24 and 25 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent 4,637,396 to Cook. That rejection is respectfully traversed.

The invention of the present application is directed to a hollow radially expandable balloon member comprising an intermediate portion located between terminal portions which have a diameter smaller than the intermediate portion and having a fluid impervious wall. The balloon member is for use with a catheter for radially expanding a vessel in the body of a mammal. The catheter comprises a tube portion with a passage therethrough and is adapted to have a hollow expandable balloon member secured to the tube portion by the smaller diameter terminal portions. In this way, the balloon member can be inflated and deflated by means of a fluid passed through the passage of the catheter. The wall of the balloon member has a substantially uniform thickness and is formed from a flexible substantially fluid impervious material having reinforcing fibers provided integrally with the wall material, which fibers act to limit the maximum radial expansion of the balloon member. The intermediate portion of the balloon member is preformed with a radial diameter which corresponds substantially to that of the balloon member at a maximum unstretched radially expanded state. The balloon member can be inflated to its maximum radial

expansion state as limited by the fibers within the wall material without causing substantial stretching of the wall material.

The Examiner asserts that Cook discloses a hollow radially expandable balloon member having terminal portions with a diameter smaller than an intermediate portion and a fluid impervious polyurethane wall having reinforcing fibers integral with the wall material which limit radial expansion of the balloon when it is inflated. Applicants respectfully disagree with the Examiner, because the feature which characterizes the present invention over prior art such as Cook is that the "intermediate portion of the balloon is preformed with a radial diameter which corresponds substantially to the balloon member at a maximum unstretched radially expanded state, whereby the balloon member can be inflated to its maximum radial expansion as limited by the fibers within the wall material without causing substantial stretching of the wall material" (see, claim 16, paragraph b).

In Cook, the balloon is stretched on inflation until it reaches its maximum radial extension as limited by the fibers in the balloon wall. The fact that the Cook balloon is stretched during inflation is clear from the disclosure at column 3, lines 27-33 and 58-62. In the present invention, there is no stretching of the balloon on inflation. Instead, because it has been preformed into its fully extended size, it only needs to be inflated rather than stretched to reach its maximum radial extension, any further radial extension beyond that dictated by the preformed balloon being limited by the fibers in the balloon wall.

In light of the above, it is clear that Cook does not anticipate (or suggest) the presently claimed invention. Withdrawal of the outstanding anticipation rejection based on Cook reference is accordingly respectfully requested.

II. THE OBVIOUSNESS REJECTIONS

Claim 20 stands rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Cook in view of U.S. Patent 3,616,199 to Breslow. Claim 23 stands rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Cook.

In response, claims 20 and 23 are each dependent on claim 16 and incorporate the patentable features of that claim, as discussed above. Cook does not anticipate or suggest claim 16 for the reasons discussed above, and thereby does not disclose or suggest the subject matter of claim 20 or claim 23.

The secondary references relied on by the Examiner do not cure the deficiency of Cook in so far as the subject matter of claim 20 or 23 is concerned. Breslow is relied upon as allegedly disclosing a fibrous polyester reinforcing material to a rubber stock, such as polyurethane. Other than that disclosure, which is not conceded, the combined disclosures of Cook and Breslow do not lead one of ordinary skill to the invention as claimed in claim 20. Likewise, Cook does not suggest the subject matter of claim 23.

A person of ordinary skill would not have been motivated to arrive at the subject matter of claim 20 or 23 based on Cook, either when taken alone or in combination with Breslow. Absent such motivation, it is clear that a *prima facie* case of obviousness has not been made out in this case. Reconsideration and withdrawal of the outstanding obviousness rejections are respectfully requested.

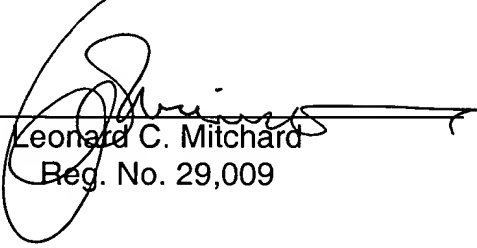
ANDREWS et al
Appl. No. 09/678,486
September 22, 2003

Allowance of the application is awaited.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____


Leonard C. Mitchard
Reg. No. 29,009

LCM:lfm
1100 North Glebe Road, 8th Floor
Arlington, VA 22201-4714
Telephone: (703) 816-4000
Facsimile: (703) 816-4100